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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,148	04/26/2001	Chester Struble	P-9440	6240

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EXAMINER
SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/842,148	STRUBLE, CHESTER	
	Examiner	Art Unit	
	Kennedy Schaetzle	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-8, 10, 11 and 13-16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cohen (Pat. No. 5,156,148).

Regarding claim 1, Cohen disclose a system for treating cardiac arrhythmia comprising a sensing lead (note col. 8, lines 38-46), a processor configured to receive electrical signals indicative of heart rate and to detect and discriminate between atrial and ventricular arrhythmias and generate an arrhythmia signal (note the paragraph abridging cols. 4 and 5, col. 6, lines 28-37, and col. 10, lines 43-55), a drug delivery system 18 configured to receive the arrhythmia signal comprising a first drug pump (e.g., element 18a) containing a first drug (note col. 7, lines 29-37 and the various drugs mentioned throughout Figs. 5A-5I), a second drug pump (e.g., element 18b) containing a second drug (again note the various drugs mentioned in the above recited figures), and first and second infusion apparatus coupled to the first and second drug pumps (the venous and/or arterial injection devices discussed in Fig. 2). The drug delivery system is configured to activate the first drug pump to dispense the first drug via the first infusion apparatus when the arrhythmia signal is indicative of atrial arrhythmia (see for

example boxes 547 and 550 of Fig. 5C), and is configured to activate the second drug pump to dispense the second drug via the second infusion apparatus when the arrhythmia is indicative of ventricular arrhythmia (see for example boxes 503 and 510 of Fig. 5B).

Regarding the use of first and second drugs, Cohen teaches that the system may employ drug(s) (note plural form) and that the various arrhythmias may be treated singly or in *combination* (col. 7, lines 18-37). Most assuredly if one was to implement the treatment defined by the flowcharts of Figs. 5A-5I which call for a variety of different drugs to be used depending upon the particular heart condition detected, one would necessarily have to provide at least first and second drug pumps containing respective first and second drugs.

Regarding the use of a sensing lead, although the examiner considers conventional EKG electrodes such as discussed by Cohen and referred to above, to pertain to leads (the examiner notes that a variety of artisans equate the term "electrodes" to the term "leads" even though such a comparison is not entirely accurate), those of ordinary skill in the art would have seen the provision of a lead or leads to obtain EKG signals for a device of the type shown in Fig. 7 to be blatantly obvious given their ubiquitous nature in implantable medical devices.

Regarding the recitations concerning the detection of cardiac arrhythmia *only* from heart rate and without regard to patient hemodynamic condition, the discrimination between an atrial arrhythmia and a ventricular arrhythmia as a function of *only* heart rate, and the generation of an arrhythmia signal as a function of the type of arrhythmia discriminated as a function of *only* the heart rate, the device of Cohen is still considered to meet these limitations because the fact that a device uses a combination of both electrical signals and physiological signals to redundantly detect, discriminate and signal (the examiner considers any output result to be a signal) arrhythmias in order to enhance diagnostic accuracy, does not negate the fact that the device is capable of separately processing each information channel to form an independent analysis of the arrhythmia type. In other words, if the electrical signals indicative of heart rate are processed in a rate-only subsystem to discriminate between an atrial arrhythmia and a

ventricular arrhythmia, and then later combined with an outcome brought on by independent analysis of the data produced by the physiological sensors, the system effectively has performed a detection, discrimination and signaling based only on the heart rate in combination with a detection, discrimination and signaling based only on the physiological signals. The examiner further wishes to direct the applicant's attention to the subject matter of claim 19 wherein electrical signals indicative of heart rate (i.e., rhythm) are used to detect cardiac arrhythmias only from heart rate and without regard to patient hemodynamic condition.

Regarding claim 4, note the atrial and ventricular channels shown in Fig. 2 that carry the electrical heart signal to the processing device. Although Cohen does not explicitly state that the atrial (or ventricular) signal is obtained from a lead located in the atrium (or ventricle), the use of an atrial lead and a ventricular lead to respectively obtain an atrial signal and a ventricular signal would clearly have been considered blatantly obvious by anyone of ordinary competence in the art, especially given that this type of arrangement is old and conventional.

Regarding claim 5, the examiner considers the CPU 13 to comprise both a processor and a controller, with the control signal being input to the various drug delivery devices 18a-18d.

Concerning claim 7, the monitor/recorder is considered to represent an input/output device (note col. 7, lines 38-43).

In reference to claim 8, the examiner considers drug delivery devices 18a-18d to represent at least four drug pumps. Again, since more than three different types of drugs have been disclosed by Cohen as available for use with the invention depending on the situation encountered, it would have been inherent that one of the drug pumps 18 would have contained a third drug.

Concerning claim 10, note box 510 of Fig. 5B.

The rejection of independent claims 11 and parallel the rejection of claim 1 above.

In reference to claim 13, the examiner considers the device of Cohen to inherently select first and second dosages of first and second drugs if it is to perform the

method set forth in Fig. 5, since it would be unethical to implant a selective drug delivery device in a patient without any control whatsoever over the dosage of drug released. In any event, the examiner took Official Notice in the previous Office Action that the selection of drug dosages and the subsequent dispensing of said dosages into the body is an old and well-known technique to deliver proper, safe and effective amounts of medication. Since the applicant has not timely traversed this Notice, the feature is considered to be admitted prior art.

Regarding claim 14, the examiner considers the gravity operated drug delivery system discussed by Cohen to be a drip dosage mechanism. In any event, those of ordinary skill in the art would have seen the particular method for drug delivery to be a matter of obvious design. Since drip and bolus dosage drug delivery techniques are clearly known by those of ordinary skill in the art, the final decision as to which system to employ rests in the hands of the system designer and is dependent upon the application at hand.

Concerning claim 15, the examiner considers the device of Cohen to dispense a bolus of a first drug in view of the fact that Webster's dictionary defines a "bolus" as simply a mass injected into a blood vessel. In any event, the particular form of the medicament injected would have been considered a matter of obvious design dependent upon the particular drug employed and the relative effectiveness of the various known delivery mechanisms.

In regards to the drug pump activating and defibrillation steps set forth in claim 15, Cohen explicitly teaches that one may apply defibrillation shocks to revert cardiac arrhythmias as is old and well-known in the art. The particular steps need not be taken in any particular order or timing sequence, and therefore any prior art method comprising these steps would read on the claim. In any event, the examiner considers the exact treatment regimen to be a physician's prerogative.

Regarding claim 16, the comments made immediately above apply here as well.

4. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen.

Regarding claim 9, Cohen does not explicitly refer to the use of a first drug selected from the group consisting of digitalis and beta blockers. Clearly the decision

as to which particular medication should be used in the treatment of the patient would reside with the patient's physician, as the physician is in the best position to ascertain the condition of the patient. Those of ordinary skill in the art would have therefore considered the exact drug to be employed from the list of known anti-arrhythmia drugs to be an obvious physician's prerogative.

Response to Arguments

5. Applicant's arguments filed September 28, 2004 have been fully considered but they are not persuasive.

The applicant argues that Cohen teaches away from rate only systems that detect and identify an arrhythmia on the basis of sensing only heart rate. The applicant remarks, "Cohen considers such systems to inadequately differentiate between hemodynamically stable and unstable rhythms. Cohen therefore teaches to combine a physiologic parameter indicative of the hemodynamic condition of the patient with an electrical rate signal derived from the heart." The examiner responds that a reference is relevant as prior art for *all* subject matter it contains. MPEP 2123 states, "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including non-preferred embodiments," (See *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989)). See also *Celeritas Technologies Ltd. v. RockwellInternational Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998).

Applicant newly argues that the position taken above by the examiner "...ignores the express language quoted from *In re Heck* that patents are relevant 'for all they contain." It is stated that the case-law relied upon by the examiner involves a situation where a disclosed, non-preferred embodiment was the basis for the rejection. The applicant argues that Cohen "...'contains' a teaching that a 'rate-only' system is not workable with his proposed treatment therapy of drug delivery," and that the teaching in Cohen is not one of a "non-preferred embodiment," but that of an unworkable embodiment. The examiner disagrees and believes the applicant is taking a very narrow view of what the phrase "...for all that it would have reasonably suggested to

one having ordinary skill in the art, including non-preferred embodiments," connotes. The applicant appears to imply that it only applies to preferred and non-preferred embodiments, but not disclosures of prior art systems that are disparaged. The disclosure of a disparaged system is still a disclosure. By analogy, a disclosure that a coal-fired locomotive is inferior to a diesel-powered locomotive does not negate the suggestion that locomotives may be powered by coal.

For the sake of argument, even if one were to accept the line of reasoning that the phrase "relevant for all they contain" only applies to working embodiments, there is no teaching in the Cohen reference that states that the rate-only system is not workable with drug treatment therapy. Cohen in fact states that rate-only systems are preferred by some because of their increased sensitivity and are thus theoretically less likely to miss ventricular tachycardias (col. 3, lines 31-44). While it is further stated that rate-only systems may be too sensitive –thus prompting the addition of hemodynamic sensors to reduce the sensitivity-- this is hardly a teaching that such systems are unworkable and says absolutely nothing in regards to the effectiveness of drug treatment. Cohen is simply saying that rate-only systems are less than optimal and offers an improvement thereon. The applicant fails to proffer any explanation as to why one of ordinary skill in the art would expect drug therapy to work with the system claimed by Cohen, but fail with rate-only arrhythmia detection systems. The application of drug therapy is independent of whether or not one has a rate-only arrhythmia detection system or a combined hemodynamic/rate-based system. In addition, no specific solution to this supposed unworkable situation has been disclosed in the present invention that would indicate that it ever was an art recognized unsolved problem. The applicant should not be rewarded with a patent for simply taking what was disparaged in the prior art and claiming it as his own.

In summary, the use of rate-only arrhythmia discrimination systems is old and well-known, as is the use of drug therapy systems to treat the arrhythmias once detected. To pair the two systems in view of the Cohen disclosure would have been reasonably suggested to one having ordinary skill in the art.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on M-F at 571 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
December 12, 2004

KENNEDY SCHAETZLE
PRIMARY EXAMINER